UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ROBERT TOWNSEND, Plaintiff, v. ALEX AZAR, in his official capacity as Secretary of the United States Department of Health and Human Services, Defendant.	Case No. 20 Civ. 1210 (ALC)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S
MOTION FOR SUMMARY JUDGMENT

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York
Counsel for Defendant
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-3274
rachael.doud@usdoj.gov

Of Counsel:

RACHAEL DOUD
Assistant United States Attorney

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Defendant Alex M. Azar, II, Secretary of the United States Department of Health and Human Services (the "Secretary"), respectfully submits this memorandum of law in support of his motion for summary judgment.

PRELIMINARY STATEMENT

Plaintiff Robert Townsend ("Plaintiff") suffers from glioblastoma multiforme ("GBM"), an incurable form of brain cancer. This case arises from an Administrative Law Judge's ("ALJ's") denial of Plaintiff's claim for Medicare coverage of certain months of tumor treatment field therapy ("TTFT"), which may be used to treat GBM. On appeal, Plaintiff argues that the Secretary is collaterally estopped from denying the TTFT claim at issue, and any other claim that may arise in the future, because certain prior ALJ decisions allowed coverage for other months of TTFT claims. Plaintiff's claim fails.

First, Plaintiff lacks standing because he fails to establish an injury in fact. While denying coverage for Plaintiff's TTFT in the decision Plaintiff challenges, the ALJ concluded that Plaintiff would not be liable for the payment, which must instead be covered by the device manufacturer. Accordingly, the challenged decision did not result in any harm to Plaintiff.

Second, the doctrine of collateral estoppel does not apply to Medicare claims appeals such as this one. In arguing that non-precedential decisions of ALJs forever estop the Secretary from denying claims for TTFT treatment, Plaintiff relies on *Astoria Federal Savings and Loan Association v. Solimino*, 501 U.S. 104 (1991), which held that administrative decisions can have preclusive effect only where not inconsistent with Congress's intent in enacting the statute at issue. *Id.* at 108. Here, collateral estoppel is foreclosed by the Medicare statute and its implementing regulations, which make clear that ALJ decisions do not have preclusive effect. Every circuit to decide the issue has rejected similar attempts to bind federal agencies to non-precedential decisions

in administrative appeals; Plaintiff, meanwhile, fails to cite a single decision supporting his contrary view.

Even if there were no bar to collateral estoppel, moreover, Plaintiff would not be entitled to collateral estoppel in this case because the required elements are not met. It would also be unfair to apply collateral estoppel to the Secretary in this case because the Secretary had no reason to believe that failing to litigate the favorable ALJ decisions in this case would result in permanent collateral estoppel on the issue. Finally, even if collateral estoppel did apply to the ALJ decision at issue, it could not apply prospectively because controlling facts have changed significantly.

For the foregoing reasons, the Secretary respectfully requests that summary judgment be granted in his favor.

BACKGROUND

A. Statutory and Regulatory Framework

1. "Reasonable and Necessary" Medical Expenses

Medicare is a federal health insurance program for people who are elderly or have disabilities. *See* 42 U.S.C. § 1395 *et seq*. For a medical service to be covered by Medicare, it must fit within a benefit category established by the Medicare statute. *Id*.

This case concerns Medicare Part B, which extends coverage to certain types of durable medical equipment ("DME") for qualified recipients. 42 U.S.C. §§ 1395k(a), 1395x(s)(6). The various benefit categories available under Medicare Part B are set forth in 42 C.F.R. part 414. Almost all Medicare coverage determinations, including those in this case, are subject to 42 U.S.C. § 1395y(a)(1)(A), which excludes certain items from coverage. Under that section, "no payment may be made under . . . part B for any expenses incurred for items or services[] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the

functioning of a malformed body member . . . ." 42 U.S.C. § 1395y. Unless there is an exception, this bar applies "[n]othwithstanding any other provision" of the Medicare statute. *Id.* § 1395y(a)(1)(A). The Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program for the Secretary, has historically interpreted "reasonable and necessary" to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. *See* Medicare Program Integrity Manual ("MPIM") § 13.5.4.[1]

The Secretary has broad discretion in administering the "reasonable and necessary" standard. *See Heckler v. Ringer*, 466 U.S. 602, 617 (1984) (citing 42 U.S.C. § 1395ff(a)). The Secretary may choose to articulate "reasonable and necessary" standards through formal regulations that have the force and effect of law throughout the administrative process. *See* 42 U.S.C. §§ 1395hh; 1395ff(a)(1). The Secretary may also choose to issue National Coverage Determinations ("NCDs") "with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B); *see also* 42 C.F.R. §§ 400.202, 405.1060. However, the Secretary is not required to promulgate regulations or policies that, "either by default rule or by specification, address every conceivable question" that may arise, *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995), and may instead choose to proceed based on individual determinations. *See Heckler*, 466 U.S. at 617.

[1] The current MPIM is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf. The MPIM "is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment." *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

2. Enforcement of the "Reasonable and Necessary" Standard Through Local Coverage Determinations

Here, the Secretary has delegated to CMS broad authority to determine whether Medicare covers particular medical services. CMS, in turn, contracts with Medicare Administrative Contractors ("MACs"), such as Noridian Healthcare Solutions in this case, to administer certain day-to-day functions of the Medicare program. 42 U.S.C. § 1395kk-1. Consistent with controlling regulations and any applicable NCDs, an MAC makes coverage determinations, issues payments, and develops Local Coverage Determinations ("LCDs") for the geographic area it serves, *see* 42 U.S.C. § 1395ff(f)(2)(B), in accordance with the reasonable and necessary provisions in 42 U.S.C. § 1395y(a)(1)(A). *See* 42 U.S.C. §§ 1395kk-1(a)(4), 1395ff(f)(2)(B). An LCD is binding only on the contractor that issued it, and only at the initial stages of the Medicare claim review process, as opposed to later stages if a claimant should appeal a determination by a MAC. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II). ALJs are not bound by LCDs, but are required to give them "substantial deference." 42 C.F.R. § 405.1062(a). If an ALJ declines to follow an LCD in a particular case, it "must explain the reasons why the policy was not followed." *Id.* § 405.1062(b). An ALJ's decision not to follow an LCD "applies only to the specific claim being considered and does not have precedential effect." *Id.*

In developing LCDs, MACs follow guidance contained in the MPIM. The MPIM requires MACs to publish LCDs that specify when "an item or service [is considered] to be reasonable and necessary." MPIM § 13.5.4. MACs develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. MPIM §§ 13.2.3, 13.5.2.1-3, .5; 66 Fed. Reg. 58,788 (Nov. 23, 2001). MACs also follow detailed procedures for issuing new or substantively revised LCDs, including

engaging in a notice-and-comment period, soliciting feedback and recommendations from the medical community, and presenting the policy in meetings of stakeholders. MPIM § 13.2.1.

3. The LCDs for TTFT Devices

In April 2011, the United States Food and Drug Administration approved the commercial distribution of a TTFT device manufactured by Novocure, Inc., and later rebranded Optune, for the treatment of recurrent GBM. (Certified Admin. Record ("CAR") 68, 149.) Following a review of the clinical literature, in October 2015, the DME MACs issued the original LCD for TTFT, indicating that TTFT was not covered for beneficiaries with GBM.[2] (CAR 149.) Another LCD that went into effect on January 1, 2017, remained substantively unchanged and stated that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." (CAR 14-15.)

On August 7, 2018, the DME MACs received a request from Novocure for reconsideration of the TTFT LCD, noting that it did not address newly diagnosed GBM. (CAR 69.) Effective September 1, 2019, the LCD was revised to permit coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances. *See* CMS, Tumor Treatment Field Therapy (TTFT), Policy Article (A52711), 09/01/2019, available at https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52711&ver=16&Date=10%2f25%2f2019&DocID=A52711&bc=hAAAABAAAAAA& (last visited June 26, 2020). Novocure was "extremely pleased" with the 2019 LCD and noted that its coverage criteria "is generally similar to Optune's commercial coverage criteria

[2] The MPIM in effect at the time the original LCD was issued is available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R473PI.pdf (Transmittal 473, dated 6/21/2013).

for newly diagnosed GBM." *See.* Medicare Releases Final Local Coverage Determination Providing Coverage of Optune® for Newly Diagnosed Glioblastoma, https://www.novocure.com/medicare-releases-final-local-coverage-determination-providing-coverage-of-optune-for-newly-diagnosed-glioblastoma/ (last visited June 26, 2020).

4. Claims and Administrative Appeals

In order for a beneficiary to challenge the denial of a claim under the Medicare statute, he or she must submit a claim for payment to the Medicare contractor. *See generally* 42 U.S.C. § 1395y(a); 42 C.F.R. § 405.904. If the claim is denied, the beneficiary must generally exhaust the following four levels of administrative review before filing suit in district court. *Id.* First, the beneficiary may seek a redetermination from the Medicare contractor, which must be performed by a person who did not make the initial decision. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.920, 405.940. At the second level, a beneficiary may seek reconsideration by a qualified independent contractor ("QIC") whose panel members must have "sufficient medical, legal, and other expertise, including knowledge of the Medicare program." 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. §§ 405.960, 405.968(c)(1). An LCD is not binding at this or higher levels of appeal. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.968(b). At the third level, a beneficiary can request a hearing before an ALJ, who issues a decision based on the evidence presented at the hearing or otherwise admitted into the administrative record by the ALJ. 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(d); 42 C.F.R. §§ 405.1000-02, 405.1042, 405.1046.

The administrative process ends in a review of the ALJ's decision by the Medicare Appeals Council (the "Council"), a division of the Departmental Appeals Board of the Department of Health and Human Services. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.1100, 405.1122. The Council's decision (or the ALJ's decision, if not reviewed by the Council)

represents the final decision of the Secretary for purposes of administrative exhaustion. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2)(A); 42 C.F.R. §§ 405.1048, 405.1130, 405.1136. If the Council does not render a decision within a specified timeframe, a beneficiary may request elevation to district court. 42 C.F.R. § 405.1132.

The claimant is entitled to judicial review of the Secretary's decision in the district court "as is provided in [42 U.S.C.] 405(g)." 42 U.S.C. § 1395ff(b)(1)(A). In such a review, the Secretary's findings of fact "if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g).

5. Advanced Beneficiary Notices

If Medicare coverage is denied to a beneficiary, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). The supplier can shift the risk of non-coverage to the beneficiary by providing him with advance written notice (called an "Advance Beneficiary Notice") of the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b). Here, the ALJ found that there was no evidence in the record (such as Plaintiff having signed an Advance Beneficiary Notice) indicating that Plaintiff should have known that the device would not be covered, so he could not be financially responsible for the TTFT claims at issue. (*See* CAR 73.)

B. Plaintiff's Claims

Plaintiff, who has recurrent GBM, sought coverage of the Optune system supplied by Novocure for dates of service on August 7, 2018, September 7, 2018, and October 7, 2018. (CAR 67.) On August 13, 2018, September 13, 2018, and October 13, 2018, MAC Noridian Healthcare Solutions denied payment of the claims. (*Id.*) On January 3, 2019, Noridian issued a

redetermination affirming the initial denial of the claims. (*Id.*) Plaintiff requested reconsideration, and on March 19, 2019, the QIC determined that the device was not covered under Medicare. (*Id.*) The QIC found the supplier, Novocure, rather than Plaintiff, liable for the claims. (*Id.*)

On April 1, 2019, Plaintiff filed a request for an ALJ hearing. (CAR 67.) ALJ Brian Butler received evidence and held a hearing on May 29, 2019. (*Id.*) On June 25, 2019, ALJ Butler issued a decision denying Plaintiff's claims for Medicare coverage of the Optune system for the period at issue (ALJ Appeal No. 1-8429561876). (Compl., Dkt. 1, ¶ 22; CAR 67-74.) ALJ Butler noted that Plaintiff had recurrent GBM, having suffered a progression of the disease in 2018 after being initially diagnosed in 2011. (CAR 68.) ALJ Butler held that, while he was not bound by the LCD that categorically denied coverage for TTFT, he was required to give it substantial deference unless there was a particular reason to deviate from it. (CAR 71-72.) ALJ Butler concluded that deviation from the LCD was not warranted, including because Plaintiff had not been using the TTFT device at the recommended usage rate. (CAR 72.) ALJ Butler also found it significant that the new LCD that had then been proposed and later went into effect in September 2019 would provide coverage only for newly diagnosed GBM, and thus would not provide coverage for Plaintiff. (CAR 73.) While ALJ Butler denied coverage for TTFT for the dates at issue, he concluded that there was no evidence to suggest that Plaintiff knew, or should have been expected to know, that the device would not be covered, and that Plaintiff thus would not be responsible for payment. (*Id.*)

Following ALJ Butler's decision, Plaintiff appealed that decision to the Medicare Appeals Counsel. (CAR 19-23.) The Medicare Appeals Counsel did not issue a decision within 90 days, and Plaintiff elected to proceed to the district court. (CAR 1); *see* 42 C.F.R. 405.1016(f). This appeal is pursuant to 42 U.S.C. §§ 405(g) and 1395ff(b) (providing for judicial review as set forth in § 405(g)). (*See* Compl. ¶ 5.)

Plaintiff attempts to rely on coverage determinations issued by other ALJs pertaining to claims for other time periods, in which those ALJs chose to depart from the applicable LCD and found that Medicare coverage was available for those particular claims. Specifically, on November 8, 2018, ALJ David Krane ordered coverage for August through October 2017 (ALJ Appeal No. 1-7737575148). (CAR 29-43.) On February 4, 2019, ALJ Thomas Tyler ordered coverage for February 7, 2018 to April 7, 2018 (ALJ Appeal No. 1-8116629727). (CAR 51-57.) On August 15, 2019, ALJ Timothy Gates ordered coverage for November 2018 through January 2019 (ALJ Appeal No. 1-8637672132). (CAR 10-17.)[3] Plaintiff also cites a January 13, 2020, decision that is not in the administrative record, in which, Plaintiff says, ALJ Carolyn Jane Van Duzer ordered coverage for February through April 2019 (ALJ Appeal No. 3-8686737932). (*See* Dkt. No. 14 at 2.)

ARGUMENT

I. Standard of Review

Even though cross-motions for summary judgment are before the Court, the standard articulated in Federal Rule of Civil Procedure 56 is inapplicable because the Court has a more limited role in reviewing the administrative record. *See Murphy v. Sec'y of Health and Human Servs.*, 62 F. Supp. 2d 1104, 1106 (S.D.N.Y. 1999). Specifically, in an appeal arising under Section 405(g), the findings of the ALJ are conclusive unless not supported by substantial evidence or based on an incorrect legal standard. *Id*. Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id.* (quoting *Richardson v.*

[3] These decisions were submitted by Plaintiff to the Medicare Appeals Counsel as part of his appeal, which was not ultimately heard because Plaintiff elected to proceed to district court without waiting for a decision.

Perales, 402 U.S. 389, 401 (1971)). The Court's review is limited to the administrative record. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A).

II. Plaintiff Lacks Standing

Standing requires that a plaintiff have "a personal stake in the outcome of the controversy [so] as to warrant his invocation of federal-court jurisdiction." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). At its "irreducible constitutional minimum," this requires a plaintiff to demonstrate that it has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). To establish injury in fact, a plaintiff must show that it "suffered an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Id.* at 1548 (citation omitted).

Here, while ALJ Butler denied Medicare coverage for the time period at issue, he did not hold Plaintiff responsible for the amount owed, which must instead be paid by the device manufacturer. (CAR 73.) Because Plaintiff does not have to pay anything, he has not suffered an injury in fact that is "actual or imminent." *Spokeo*, 136 S. Ct. at 1548 ("[A] bare procedural violation, divorced from any concrete harm, [does not] satisfy the injury-in-fact requirement of Article III"); *see also Thole v. U.S. Bank N.A.*, 140 S. Ct. 1615, 1619-20 (2020) (plaintiffs did not have standing notwithstanding the fact that ERISA afforded them a cause of action to sue because they would receive the same payments whether they won or lost). Accordingly, Plaintiff lacks standing. This alone is dispositive of Plaintiff's case and warrants dismissal.

III. The Common Law Doctrine of Collateral Estoppel Is Inapplicable

Even if Plaintiff did not lack standing, Defendant would still be entitled to summary judgment because Plaintiff's central argument—that prior ALJ decisions estopped any denial of

coverage—fails. This is so for two reasons. First, collateral estoppel is inapplicable to administrative determinations in this context. Second, the elements of collateral estoppel have not been met.

A. Collateral Estoppel is Inapplicable to ALJ Decisions in Medicare Claim Appeals

In arguing that prior ALJ decisions should have preclusive effect, Plaintiff relies heavily on the Supreme Court's decision in *Astoria*, in which the Court indicated that collateral estoppel may, in some circumstances, be based on agency determinations when the agency is acting in a "judicial capacity." *Astoria*, 501 U.S. at 107-08; Dkt. No. 14 at 3; Compl. ¶¶ 1, 10. Plaintiff fails to acknowledge, however, that the Court in *Astoria* held that agency decisions should not be given preclusive effect when there is a contrary legislative intent and that, applying that principle, the agency decision at issue in that case had no preclusive effect. 501 U.S. at 106-108.[4] Here, likewise, the Medicare statute and regulations make clear that ALJ coverage determinations do not have preclusive effect.

1. *Federal Regulations Provide that ALJ Decisions Do Not Bind the Secretary in Future Cases*

As an initial matter, the Medicare statute and regulations make explicit that ALJ decisions are not meant to have preclusive effect. The Medicare regulations sharply distinguish between a narrow category of decisions that are intended to be precedential and thus binding on future administrative appeals and any other decisions, which are non-precedential and not binding. Specifically, in Medicare coverage cases, only Council-level decisions have the potential to become precedential, and even those decisions are precedential only if they are so designated by

[4] *United States v. Stauffer Chem. Co.*, 464 U.S. 165 (1984), the other case Plaintiff cites in his complaint, addressed the question of whether the government was collaterally estopped based on a prior *court* decision (there, a decision of the Tenth Circuit Court of Appeals). *Id.* at 170-74.

the Chair of the Departmental Appeals Board. 42 C.F.R. § 401.109. Council decisions designated as precedential must be made available to the public, with personally identifiable information removed, and notice of precedential decisions must be published in the Federal Register. 42 C.F.R. § 401.109(b). Those decisions are then given "precedential effect" and are binding on "all HHS components that adjudicate matters under the jurisdiction of CMS." *Id.* § 401.109(c). The term "precedential effect" means that the Council's:

> (1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and
>
> (2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

Id. § 401.109(d). Accordingly, the term "precedential effect" is synonymous with a decision having binding or preclusive effect. *See Taransky v. Sec. U.S. Dep't of Health & Human Servs.*, 760 F.3d 307, 319 (3d Cir. 2014) (noting that the Medicare Appeals Council was free to depart from prior decisions of ALJs because only Appeals Council decisions "have legal significance"). It is undisputed that no Council decision, much less one designated as precedential, has been rendered with respect to Plaintiff's claims.

The regulations governing LCDs further support that ALJ decisions are nonbinding and collateral estoppel is therefore inapplicable. Specifically, Plaintiff's collateral estoppel argument relies upon favorable ALJ decisions that departed from the applicable LCD when approving TTFT treatment. But governing regulations explicitly provide that an ALJ's decision to depart from an LCD "applies only to the specific claim being considered and does not have precedential effect." 42 C.F.R. § 405.1062(b); 70 Fed. Reg. 11420, 11458 (Mar. 8, 2005) ("[T]he ALJ or [Council] may

decline to follow a policy in a particular case, but must explain the reason why the policy was not followed. These decisions apply only for purposes of the appeal in question, and do not have precedential effect."). These regulations reaffirm that only "[p]recedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding . . . ." 42 C.F.R. § 405.1063(c). Indeed, ALJ decisions are not even binding on lower levels of administrative review, such as the QIC second level of review. *See* 42 C.F.R. § 405.968(b) (omitting ALJ decisions among the rulings that bind the QIC).

Giving preclusive effect to ALJ decisions is also contrary to the Medicare statute itself, which provides that the Council must "review the case de novo." 42 U.S.C. § 1395ff(d)(2)(B). If a favorable ALJ ruling collaterally estopped the Council from denying a beneficiary's claim for the same treatment, the Council could not perform a *de novo* review; instead, the Council would be bound to accept the ALJ's conclusions. *See Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012) (rejecting challenge to denial of Medicare Part B coverage for device, reasoning in part that the Council's obligation to undertake "de novo" review was "incompatible with [plaintiff's] proffered notion that the [Council] is somehow obligated to defer to the outcomes of prior decisions below").

This is in line with the guidance from The Restatement (Second) of Judgments § 83 (1982) that:

> (4) An adjudicative determination of an issue by an administrative tribunal does not preclude relitigation of that issue in another tribunal if according preclusive effect to determination of the issue would be incompatible with a legislative policy that:
>
> > (a) The determination of the tribunal adjudicating the issue is not to be accorded conclusive effect in subsequent proceedings; or
> >
> > (b) The tribunal in which the issue subsequently arises be free to make an independent determination of the issue in question.

Medicare regulations explicitly state that ALJ decisions are not to be accorded conclusive

effect as they are non-precedential, and the Council's *de novo* review means that it is free to make an independent determination. Accordingly, the Medicare statute and regulations bar the application of collateral estoppel to ALJ decisions.

2. *Applying Collateral Estoppel Would Interfere with the Discretion and Deference Afforded to the Secretary to Implement the Medicare Statute*

Deeming ALJ decisions binding on future coverage determinations would also run contrary to the deference and discretion afforded to the Secretary to implement the Medicare statute, particularly as pertains to the "reasonable and necessary" standard for coverage of items and services furnished to program beneficiaries.

"[T]he choice made between proceeding by general rule or by individual, ad hoc litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). Here, the Medicare statute and regulations preserve "this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process." *Almy*, 679 F.3d at 303. The Supreme Court has foreclosed arguments that interfere with this discretion, holding that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Ringer*, 466 U.S. at 617; *see also Guernsey Mem'l Hosp.*, 514 U.S. at 97 ("The Secretary's mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate.").

As noted above, the Medicare regulations designate ALJ decisions as non-binding and non-precedential, which allows individual adjudication over Part B claims. This often inures to the

benefit of Medicare beneficiaries, who, even after repeated denials of similar claims, have the right to *de novo* review of any subsequent claims. The application of collateral estoppel would be fundamentally inconsistent with individual adjudication of Part B claims. In Plaintiff's view, once a claim for benefits is approved, the Secretary would be estopped from ever denying a claim for the same treatment. (Compl. ¶¶ 1-4; Dkt. No. 14 at 1, 3.) Individual adjudication would be impossible, because the earliest-in-time ALJ ruling would forever bind the Secretary. Accordingly, it is within the Secretary's discretion not to be bound by ALJ rulings. *See generally Ringer*, 466 U.S. at 607-08 (distinguishing between ALJ and Council-level decisions that "applied only to the claimants involved in that case and [were] not to be cited as precedent in future cases" and a subsequent formal administrative ruling by the Secretary that bound ALJs and the Council).

Here, the Secretary's decision that ALJ determinations are non-binding and non-precedential is expressed in the plain, unambiguous language of the applicable law and regulations. *See Avalon Place Trinity*, DAB No. 2819, at 13 (2017) ("[An] unappealed ALJ decision [does not set] a precedent binding on ALJs or the Board. When the Board has not reviewed the ALJ decision, the Board has not issued a decision in that case. Regardless of whether an ALJ decision was appealed to the Board, an ALJ decision is not precedential and does not bind the Board, and is relevant in later cases only to the extent its reasoning is on point and persuasive."), *aff'd*, *Avalon Place Trinity v. HHS*, 761 F. App'x 407 (5th Cir. Mar. 4, 2019). Because giving preclusive effect to ALJ rulings would contravene the Secretary's choice to proceed by individual determinations, the Court should decline to apply collateral estoppel here.

While Plaintiff fails to cite any cases on point,[5] the Third, Fourth, Fifth, Seventh, Ninth,

[5] Plaintiff's reliance on the unpublished decision in *Brewster v. Barnhart*, 145 F. App'x 542 (6th Cir. 2005) (Dkt. No. 14 at 3), is misplaced. There, the court found that, under circumstances

and D.C. Circuits have each rejected similar attempts to bind federal agencies to non-precedential decisions in lower-level administrative appeals. *See Taransky*, 760 F.3d at 319; *Almy*, 679 F.3d at 299-310; *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012) (reversing district court opinion that "incorrectly measured agency inconsistency across" ALJ decisions); *Abraham Lincoln Mem'l Hosp. v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012) ("The handful of prior Board decisions the Hospitals rely upon to purportedly show HHS's long-standing policy are not determinative. Our precedent instructs that Board decisions are not the decisions of the Secretary or her Administrator and are not authoritative."); *Cmty. Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003) ("There is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level."); *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir. 1987) ("'The Secretary's position' is the position of the Department as an entity, and the fact that people in the chain of command have expressed divergent views does not diminish the effect of the agency's resolution of those disputes. An inconsistent administrative position means flip-flops by the agency over time, rather than reversals within the bureaucratic pyramid."); *Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) ("[T]he decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling.").

In *Almy*, the plaintiff challenged decisions of the Medicare Appeals Counsel denying coverage for a medical device, arguing that the decisions created a policy of denying treatment for that device and the Secretary should have implemented that policy prospectively. 679 F.3d at 299,

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unique to Social Security disability appeals, an applicant (not the government) was bound by an ALJ's earlier finding concerning the exertion level of the applicant's past work. *Id.* at 546-48.

303. The Fourth Circuit disagreed, noting that "[t]he Secretary's own regulations make clear that any policy implications in an adjudication do not have precedential effect . . . . The purported 'policy' in this case is nothing more than the accretion of individual decisions finding that the [device] does not meet the statutory requirements for coverage." *Id.* at 303 (citing 42 C.F.R. § 405.1062). The court noted that Congress gave the Secretary discretion to "decide how to deal with hundreds of millions of Part B claims for coverage of thousands of devices every year." *Id.* at 304. This Court should likewise reject Plaintiff's attempt to elevate non-precedential ALJ opinions to binding coverage rules, which would "stultify the administrative process." *Id.* (quoting *Chenery*, 332 U.S. at 202).

In *Almy*, the Court noted that other circuits have concluded that "[t]here is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level . . . [E]ven if these cases were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently." *Id.* at 310 (quoting *Comty. Care Found.*, 318 F.3d at 227). Along these same lines, the Third Circuit rejected the argument that the Medicare Appeals Council was bound by prior ALJ rulings recognizing "the validity of almost identical orders," explaining that "the Appeals Council is free to depart from these lower agency rulings without concern, as only its decisions have legal significance." *Taransky*, 760 F.3d at 319. Similarly, the D.C. Circuit has emphasized its "well-established view that an agency is not bound by the actions of its staff if the agency has not endorsed those actions." *Comcast Corp. v. FCC*, 526 F.3d 763, 769 (D.C. Cir. 2008) (citing cases). Instead, "a definitive and binding statement on behalf of the agency must come from a source with the authority to bind the agency." *Devon Energy Corp. v. Kempthorne,* 551 F.3d 1030, 1040 (D.C. Cir. 2008); *see also Freeman v. U.S. Dep't of the Interior*, 37 F. Supp. 3d 313, 344-45 (D.D.C. 2014) ("unappealed"

ALJ rulings could not estop the United States because such rulings were not binding on the agency and lack of appeal did not "elevate them to the level of a binding final agency action").

The Ninth Circuit explicitly adopted the reasoning in *Almy*, reversing a district court decision that "incorrectly measured agency inconsistency across" ALJ decisions. *Int'l Rehab. Sci. Inc.*, 688 F.3d at 1001; *see also Cnty. of Los Angeles v. Leavitt*, 521 F.3d 1073, 1079 (9th Cir. 2008) (noting that "intermediary interpretations are not binding on the Secretary, who alone makes policy"). The Fifth Circuit reached the same conclusion. *See Homan & Crimen, Inc.*, 626 F.2d at 1205 ("[T]he decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling.").

In sum, "Congress has delegated broad authority to the Secretary to determine when a device is reasonable and necessary, as well as broad authority to select the procedures used for making that determination." *Almy*, 679 F.3d at 311. The doctrine of collateral estoppel cannot transform an ALJ ruling from a decision by an intermediate-level tribunal that is only binding in a single case to an officially binding statement of policy by the Secretary. To do so would be contrary to the Medicare statute and regulations.

3. *Collateral Estoppel Is Contrary to the Medicare Act's Presentment and Channeling Requirements*

Plaintiff's argument that the Secretary is collaterally estopped by favorable ALJ decisions as to future claims for TTFT is also contrary to the Medicare Act's presentment and channeling requirements.

In *Porzecanski v. Azar*, 943 F.3d 472 (D.C. Cir. 2019), the D.C. Circuit recently held that the Medicare statute prohibits a Medicare beneficiary from obtaining "prospective equitable relief

mandating that HHS recognize his treatment as a covered Medicare benefit in all future claim determinations." *Id.* at 475. The facts in *Porzecanksi* are similar to those in the instant case. Porzecanski suffered from a rare, life-threatening condition with no known cure and started on an experimental regimen of a biological product. *Id.* at 476. After one of his claims was denied at the ALJ level and the Council did not render a decision within the required time frame, the plaintiff filed in federal court. *Id.* at 477. While the federal case was pending, the plaintiff continued to submit monthly Medicare claims, which were approved by a QIC or ALJ. *Id*. On appeal of his denied claim, the plaintiff sought declaratory and injunctive relief confirming his entitlement to Medicare coverage for the product and requiring the Secretary to provide Medicare benefits. *Id.*

The D.C. Circuit held that the plaintiff could not "satisfy § 405(g)'s presentment requirement with respect to future claims because those claims have not yet arisen." *Id.* at 482. Because Medicare claims can only be filed after the medical service has been furnished, and Section 405(g) requires appeals from "decision[s]" of the Secretary, the presentment requirement could not be met: "[T]he Secretary has not decided [plaintiff's] future claims because—to state the obvious—none has been submitted." *Id.* The court thus rejected the plaintiff's request to preclude the Secretary from concluding that future claims were not covered by Medicare—the same relief that Plaintiff seeks here. *Id.* at 482 (finding plaintiff's "strained position" to be "at odds with Supreme Court precedent."). In support, the D.C. Circuit relied on two Supreme Court decisions: *Ringer* and *Illinois Council*. In *Ringer*, "the Court held that § 405(g) barred a patient from obtaining declaratory and injunctive relief compelling the Secretary to conclude that his future surgery was 'reasonable and necessary' under the Medicare Act." *Id.* (citing 466 U.S. at 620-21). Although the patient sought equitable relief, it was "essentially one requesting the payment of benefits," which constitutes a "claim arising under" the Medicare Act. *Id.* at 482-83 (quoting

Ringer, 466 U.S. at 620-21). Likewise, in *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1 (2000), the Court declared that a "claim for future benefits is a § 405(h) claim" and "all aspects" of any future claim "must be channeled through the administrative process." *Id.* (citing *Illinois* Counsel, 529 U.S. at 12). The D.C. Circuit thus concluded, "*Ringer* and *Illinois Council* directly foreclose [plaintiff's] attempt to recast the requested relief as anything other than a claim for future benefits." *Id*. Likewise, Plaintiff's assertion that the Secretary is estopped from denying his future claims for TTFT treatment "runs headlong into the Supreme Court's instruction that 'all aspects' of a claim be first channeled through the agency." *Id.* (quoting *Illinois Council*, 529 U.S. at 12). Plaintiff cannot leverage a favorable ALJ decision to estop the Secretary from denying "future claims for the same reasons." *Id.* at 483-84.

B. The Elements of Collateral Estoppel Are Not Met

"A party seeking to invoke collateral estoppel must establish that (1) the identical issue was raised in a previous proceeding; (2) the issue was actually litigated and decided in the previous proceeding; (3) the party had a full and fair opportunity to litigate the issue; and (4) the resolution of the issue was necessary to support a valid and final judgment on the merits." *In re Snyder*, 939 F.3d 92, 100 (2d Cir. 2019). Plaintiff cannot meet that standard here.

Plaintiff attempts to point to two earlier ALJ decisions—ALJ Appeal No. 1-7737575148 and ALJ Appeal No. 1-8116629727—as supposedly estopping the denial of the claims at issue. (*See* Compl. ¶ 21 (citing ALJ Appeal No. 1-8116629727); Dkt. No. 14 at 2 (citing ALJ Appeal No. 1-7737575148).) Those decisions did not involve the identical issue as in this case, however, because each decision was limited to coverage for a specific period of time.[6] Specifically, ALJ

[6] While Plaintiff also attempts to rely on ALJ decisions issued *after* the one challenged in this case (*see* Dkt. No. 14 at 2), collateral estoppel can only be based on a prior decision. *See In re Snyder*,

Appeal No. 1-7737575148 involved a coverage determination for August through October 2017 and ALJ Appeal No. 1-8116629727 involved a coverage determination for February 7, 2018 to April 7, 2018, while the ALJ decision challenged here involved a coverage determination for August through October 2018. Each decision specified that it pertained only to the coverage period at issue. (*See* CAR 43, 51, 68.) The issues raised in the different appeals also are not identical because each appeal involved its own submission of evidence and hearing, and the facts relevant to the determinations—for example the LCDs in effect at the time and the medical literature—evolve over time. (*See generally* CAR 143 (Plaintiff's attorney noting that "medicine and science progress").) For example, as ALJ Butler noted, at the point he issued his decision the LCD that would later provide coverage for newly-diagnosed GBM, but not recurrent GBM, had been proposed—a fact ALJ Butler found significant. (CAR 73.) Because each ALJ appeal did not address the same issue, collateral estoppel does not apply. *See, e.g.*, *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 435 F.3d 1356, 1361-62 (Fed. Cir. 2006) (declining to apply collateral estoppel where patent infringement involved two distinct time periods). Collateral estoppel is also inapplicable because, for the same reasons, the same issue was not actually litigated. *See Interoceanica Corp. v. Sound Pilots, Inc.*, 107 F.3d 86, 91-92 (2d Cir. 1997) (finding issue not actually litigated or decided where prior decision explicitly stated it did not reach an issue); *see also California Cmtys. Against Toxics v. EPA*, 928 F.3d 1041, 1052 (D.C. Cir. 2019) (finding issues not actually litigated where court stated it "need not address" the issue).

The third element of collateral estoppel also is not met because the Secretary's opportunity

939 F.3d at 100 (issue must have been raised, litigated and decided in a "previous proceeding"). At any rate, the subsequent decisions Plaintiff cites also pertained to different time periods from that at issue, so would not have collateral estoppel effect even if issued before the decision challenged here.

to litigate is limited in Medicare coverage appeals. The Secretary cannot participate in the first two levels of the administrative appeals process. *See* 42 C.F.R. §§ 405.948, 405.968. *See Genesis Health Ventures, Inc. v. Sebelius*, 798 F. Supp. 2d 170, 182 (D.D.C. 2011) ("[I]f an intermediary finds coverage and pays a claim, there is never an administrative appeal, and the Secretary would have no knowledge of the intermediary's decision nor opportunity to review those actions."). The Secretary's participation is also limited in ALJ appeals. When a beneficiary is unrepresented, the Secretary cannot be a party to the hearing. 42 C.F.R. § 405.1012(a). If the Secretary does not affirmatively elect to participate or become a party in ALJ proceedings, the proceedings move forward without the Secretary's involvement. 42 C.F.R. §§ 405.1010(a), 405.1012(b). Although the Secretary may participate or become a party in ALJ hearings involving beneficiaries represented by counsel, it is impracticable for the Secretary to litigate thousands of Medicare claim appeals filed each year at the ALJ level. 42 C.F.R. §§ 405.1010(a), 405.1012(a). *See* U.S. Government Accountability Office Report at 1, 12 (May 2016), https://www.gao.gov /assets/680/677034.pdf (last visited April 17, 2020); *see also* 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017) (noting that there were 650,000 pending ALJ appeals as of September 2016); *Am. Hosp. Assoc. v. Azar*, 14-cv-851, Dkt. No. 96 (Mar. 25, 2020 Status Report) (for FY 2018, over 575,000 ALJ appeals pending and over 60,000 ALJ appeals received). If the Secretary does not become a party to an ALJ hearing, he cannot appeal a favorable ruling to the Council. 42 C.F.R. §§ 405.1012, 405.1102(a)(1), (d). In other words, the Secretary would need to litigate every ALJ hearing in order to have the right to appeal any decisions favorable to the beneficiary. Accordingly, because the Secretary's opportunity to appeal was extremely limited, there was not a full and fair opportunity to litigate.

Finally, even if the Court were to conclude that Plaintiff has established the required

elements, courts have recognized an exception to preclusion even where all the elements for estoppel are met. Specifically, where there is an incentive against litigating smaller matters because the cost outweighs the significance of the issue, it is unfair to allow the decisions in those smaller matters to have large preclusive effects. *See Power Integrations v. Semiconductor Components Indus.*, 926 F.3d 1306, 1312, 1313 (Fed. Cir. 2019) (holding that the exception of "a lack of opportunity or incentive to litigate the first action" prevented preclusion where there was a disparity in incentives to appeal an issue); *Rawls v. Daughters of Charity of St. Vincent De Paul, Inc.*, 491 F.2d 141, 148 (5th Cir. 1974) (no preclusive effect given to habeas corpus hearing finding involuntary hospitalization was illegal in subsequent suit against hospital for false imprisonment because the hospital "had far less incentive to contest the unlawfulness of the plaintiff's detention than at present"). Such is the case here, where the Secretary's involvement in the litigation of every claim would be an inefficient use of resources better put towards the Medicare program. Unreviewed and non-precedential ALJ decisions should not be given preclusive effect, which would result in great cost to Medicare.

C. Even If Collateral Estoppel Applied, It Would Have No Further Force After the New LCD Became Effective on September 1, 2019

Even if collateral estoppel applied here, it would have no force after the new LCD became effective on September 1, 2019. Collateral estoppel generally will not apply when "controlling facts or legal principles have changed significantly since the [prior] judgment." *Montana v. United States*, 440 U.S. 147, 155 (1979). Here, there was a significant change between the old LCD, which categorically denied coverage for TTFT treatment, and the new LCD, which allows coverage of TTFT under certain circumstances. Accordingly, if Plaintiff was to prevail on collateral estoppel, only the ALJ decision challenged in this case would be affected. Further

preclusive or injunctive relief would not be warranted, because the new LCD has already been in place for over nine months.

Similarly, the medical context of this case necessarily means that the controlling facts are constantly changing. Physicians do not prescribe treatment, no matter how potentially effective, indefinitely into the future. A treatment that may have been beneficial for a patient at one point in time could be ineffective or dangerous if continued (for example, when a patient suffers serious side effects). In this case, there is no evidence that the facts supporting Plaintiff's claim for coverage for August through October 2018 will continue indefinitely into the future. Even if Plaintiff's medical history remained unchanged for two years, it would be pure speculation to assert that the facts would remain unchanged for any claim Plaintiff might file in the future.

IV. To the Extent Plaintiff Makes Any Other Arguments for Reversal in His Motion, Those Arguments Fail

It appears that Plaintiff intends in his motion for summary judgment to raise the sole argument that ALJ Butler was barred by collateral estoppel from denying coverage for the period at issue. (*See* Dkt. No. 14.) If Plaintiff's motion is limited to that argument, any other arguments are waived. *See Graves v. Finch Pruyn & Co.*, 457 F.3d 181, 184 (2d Cir. 2006) (arguments not raised on appeal are waived).

In any event, even if Plaintiff's motion does raise the other arguments referenced in the complaint, those arguments fail. Plaintiff's sole claim under 42 U.S.C. § 405(g) is that ALJ Butler's decision was contrary to law (Compl. Count I)—presumably based on the erroneous argument, addressed above, that it was barred by collateral estoppel. The remainder of the claims in Plaintiff's complaint are asserted under the Administrative Procedure Act ("APA"). (*See* Compl. Counts II-VI.) The APA does not apply here, however, because this appeal is pursuant to

42 U.S.C. § 1395ff(b), which permits judicial review in accordance with 42 U.S.C. § 405(g). Section 405(g), in turn, provides for review under the substantial evidence standard—not any other standard that may be provided for by the APA. *See Pierce v. Leavitt*, No. 05-36176, 2007 WL 2193761, at *1 (9th Cir. Aug. 1, 2007) (rejecting plaintiff's assertion that APA "arbitrary and capricious" standard applies to Section 405(g) cases); *Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000) (concluding that Section 405(g) cases are not governed by the APA standard of review); *Diapulse Corp. v. Sebelius*, No. 06-cv-2226 (DLI), 2010 WL 1037250, at *6 (E.D.N.Y. Jan. 21, 2010) (same); s*ee also* 5 U.S.C. § 704 (providing for review of agency actions only where there is "no other adequate remedy in a court"). Even if the APA did apply, there is no evidence to suggest that the ALJ's decision was "unlawfully withheld or unreasonably delayed"; "arbitrary and capricious, [an] abuse of discretion, [or] not in accordance with law"; "in excess of statutory jurisdiction, authority, or limitations or short of statutory right"; or "without observance of procedure required by law." (Compl. at 7-8.)

To the extent Plaintiff may attempt to challenge the ALJ's decision pursuant to 42 U.S.C. § 405(g) based on the argument that it was not supported by substantial evidence, that argument would also fail. ALJ Butler's decision was based on the LCD that was then in effect, to which the ALJ owed deference; the fact that even the new LCD would not cover Plaintiff's recurrent GBM; and the fact that Plaintiff used his device at a rate significantly below what was recommended. (CAR 67-74.) This is "such relevant evidence as a reasonable mind might accept as adequate to support" the conclusion that coverage was not warranted. *Richardson*, 402 U.S. at 401.

CONCLUSION

For the reasons above, the Secretary respectfully requests that the Court grant his motion for summary judgment and dismiss Plaintiff's claims with prejudice.

Dated: June 26, 2020
New York, New York

Respectfully submitted,

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York

By: */s/ Rachael Doud*
RACHAEL DOUD
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2697
Facsimile: (212) 637-2717
E-mail: rachael.doud@usdoj.gov